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PTO/SB/01 (12-97)

Approved for use through 9/30/00. OMB 0651-0032

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**DECLARATION FOR UTILITY OR  
DESIGN  
PATENT APPLICATION  
(37 CFR 1.63)**

Declaration Submitted with Initial Filing      OR       Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

|                          |                 |
|--------------------------|-----------------|
| Attorney Docket Number   | 455-020         |
| First Named Inventor     | JEFFREY S. KIEL |
| <b>COMPLETE IF KNOWN</b> |                 |
| Application Number       | /               |
| Filing Date              |                 |
| Group Art Unit           |                 |
| Examiner Name            |                 |

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**DIPHENHYDRAMINE TANNATE SOLID DOSE COMPOSITIONS AND METHODS OF USE**

the specification of which

*(Title of the Invention)*

is attached hereto

OR

was filed on (MM/DD/YYYY)  as United States Application Number or PCT International

Application Number  and was amended on (MM/DD/YYYY)  (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

| Prior Foreign Application Number(s) | Country | Foreign Filing Date (MM/DD/YYYY) | Priority Not Claimed                                                                                         | Certified Copy Attached?                                                                                     |
|-------------------------------------|---------|----------------------------------|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
|                                     |         |                                  | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> |

Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

| Application Number(s) | Filing Date (MM/DD/YYYY) |                                                                                                                                                  |
|-----------------------|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
|                       |                          | <input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto. |

[Page 1 of 2]

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| <b>COMPLETE IF KNOWN</b> |                 |
| Application Number       | /               |
| Filing Date              |                 |
| Group Art Unit           |                 |
| Examiner Name            |                 |

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I believe I am the original, first and sole Inventor (if only one name is listed below) or an original, first and joint Inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**DIPHENHYDRAMINE TANNATE SOLID DOSE COMPOSITIONS AND METHODS OF USE**

The specification of which

(Title of the Invention)

 is attached hereto

OR

 was filed on (MM/DD/YYYY) [redacted]

as United States Application Number or PCT International

Application Number [redacted] and was amended on (MM/DD/YYYY) [redacted] (if applicable).

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I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or Inventor's certificate, or 365(a) of any PCT International application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or Inventor's certificate, or of any PCT International application having a filing date before that of the application on which priority is claimed.

| Prior Foreign Application Number(s) | Country | Foreign Filing Date (MM/DD/YYYY) | Priority Not Claimed     | YES                      | NO                                  |
|-------------------------------------|---------|----------------------------------|--------------------------|--------------------------|-------------------------------------|
|                                     |         |                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
|                                     |         |                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
|                                     |         |                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
|                                     |         |                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

 Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

| Application Number(s) | Filing Date (MM/DD/YYYY) | <input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto. |
|-----------------------|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
|                       |                          |                                                                                                                                                  |

(Page 1 of 2)

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## DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT International application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

| U.S. Parent Application or PCT Parent Number | Parent Filing Date (MM/DD/YYYY) | Parent Patent Number (if applicable) |
|----------------------------------------------|---------------------------------|--------------------------------------|
| PCT/US03/05664<br><br>10/119,285             | 02/26/2003<br><br>04/09/2002    |                                      |

Additional U.S. or PCT International application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.  
As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:  Customer Number **001009** →  Place Customer Number Bar Code Label here  
 Registered practitioner(s) name/registration number listed below

| Name | Registration Number | Name | Registration Number |
|------|---------------------|------|---------------------|
|      |                     |      |                     |

Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.  
Direct all correspondence to:  Customer Number or Bar Code Label **001009** OR  Correspondence address below

|         |           |                |     |                |
|---------|-----------|----------------|-----|----------------|
| Name    |           |                |     |                |
| Address |           |                |     |                |
| Address |           |                |     |                |
| City    | State     | ZIP            |     |                |
| Country | Telephone | (859) 252-0889 | Fax | (859) 252-0779 |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

|                                                                                                                                              |                                                                               |       |                        |         |       |             |      |  |
|----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|-------|------------------------|---------|-------|-------------|------|--|
| Name of Sole or First Inventor:                                                                                                              | <input type="checkbox"/> A petition has been filed for this unsigned inventor |       |                        |         |       |             |      |  |
| Given Name (first and middle [if any])                                                                                                       |                                                                               |       | Family Name or Surname |         |       |             |      |  |
| JEFFREY S.                                                                                                                                   |                                                                               |       | KIEL                   |         |       |             |      |  |
| Inventor's Signature                                                                                                                         |                                                                               |       |                        |         |       |             | Date |  |
| Residence: City                                                                                                                              | GAINESVILLE                                                                   | State | GA                     | Country | US    | Citizenship | US   |  |
| Post Office Address                                                                                                                          | 4253 CHEROKEE TRAIL                                                           |       |                        |         |       |             |      |  |
| Post Office Address                                                                                                                          |                                                                               |       |                        |         |       |             |      |  |
| City                                                                                                                                         | GAINESVILLE                                                                   | State | GA                     | Zip     | 30504 | Country     | US   |  |
| <input type="checkbox"/> Additional inventors are being named on the supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto |                                                                               |       |                        |         |       |             |      |  |

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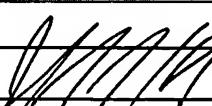
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| U.S. Parent Application or PCT Parent Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Parent Filing Date (MM/DD/YYYY) | Parent Patent Number<br>(if applicable)                                       |     |                       |            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------------------------------------------|-----|-----------------------|------------|
| PCT/US03/05664<br><br>10/119,285                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 02/26/2003<br><br>04/09/2002    |                                                                               |     |                       |            |
| <input type="checkbox"/> Additional U.S. or PCT International application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.                                                                                                                                                                                                                                                                                                                                                                            |                                 |                                                                               |     |                       |            |
| As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: <input checked="" type="checkbox"/> Customer Number <input style="border: 1px solid black; width: 100px; height: 15px;" type="text" value="001009"/> → <span style="float: right;"><i>Place Customer Number Bar Code Label here</i></span><br><input type="checkbox"/> Registered practitioner(s) name/registration number listed below |                                 |                                                                               |     |                       |            |
| Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Registration Number             | Name                                                                          |     |                       |            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                 |                                                                               |     |                       |            |
| <input type="checkbox"/> Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.                                                                                                                                                                                                                                                                                                                                                                                |                                 |                                                                               |     |                       |            |
| Direct all correspondence to: <input checked="" type="checkbox"/> Customer Number or Bar Code Label <input style="border: 1px solid black; width: 100px; height: 15px;" type="text" value="001009"/> OR <input type="checkbox"/> Correspondence address below                                                                                                                                                                                                                                                                             |                                 |                                                                               |     |                       |            |
| Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                 |                                                                               |     |                       |            |
| Address                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                 |                                                                               |     |                       |            |
| Address                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                 |                                                                               |     |                       |            |
| City                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | State                           | ZIP                                                                           |     |                       |            |
| Country                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Telephone                       | (859) 252-0889                                                                | Fax | (859) 252-0779        |            |
| I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.                                                                 |                                 |                                                                               |     |                       |            |
| Name of Sole or First Inventor:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                 | <input type="checkbox"/> A petition has been filed for this unsigned inventor |     |                       |            |
| Given Name (first and middle [if any])                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                 | Family Name or Surname                                                        |     |                       |            |
| JEFFREY S.                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                 | KIEL                                                                          |     |                       |            |
| Inventor's Signature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                 |                                                                               |     | Date <u>6/10/2001</u> |            |
| Residence: City                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | GAINESVILLE                     | State                                                                         | GA  | Country US            |            |
| Post Office Address                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 4253 CHEROKEE TRAIL             |                                                                               |     |                       |            |
| Post Office Address                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                 |                                                                               |     |                       |            |
| City                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | GAINESVILLE                     | State                                                                         | GA  | Zip 30504             | Country US |
| <input type="checkbox"/> Additional inventors are being named on the _____ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto                                                                                                                                                                                                                                                                                                                                                                                        |                                 |                                                                               |     |                       |            |

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PTO/SB/02A (11-00)

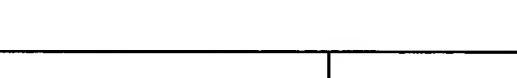
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## DECLARATION

### ADDITIONAL INVENTOR(S) Supplemental Sheet Page 1 of 1

|                                                                                                             |                      |                                                                               |                          |
|-------------------------------------------------------------------------------------------------------------|----------------------|-------------------------------------------------------------------------------|--------------------------|
| Name of Additional Joint Inventor, if any:                                                                  |                      | <input type="checkbox"/> A petition has been filed for this unsigned inventor |                          |
| Given Name (first and middle [if any])<br><u>H. GREG</u>                                                    |                      | Family Name or Surname<br><u>THOMAS</u>                                       |                          |
| Inventor's Signature<br>   | Date <u>06/07/04</u> |                                                                               |                          |
| Residence: City <u>VILLA RICA</u>                                                                           | State <u>GA</u>      | Country <u>US</u>                                                             | Citizenship <u>US</u>    |
| 29 BROOKSIDE WAY<br>Mailing Address                                                                         |                      |                                                                               |                          |
| Mailing Address                                                                                             |                      |                                                                               |                          |
| City <u>VILLA RICA</u>                                                                                      | State <u>GA</u>      | ZIP <u>30180</u>                                                              | Country <u>US</u>        |
| Name of Additional Joint Inventor, if any:                                                                  |                      | <input type="checkbox"/> A petition has been filed for this unsigned inventor |                          |
| Given Name (first and middle [if any])<br><u>NARASIMHAN</u>                                                 |                      | Family Name or Surname<br><u>MANI</u>                                         |                          |
| Inventor's Signature<br> | Date                 |                                                                               |                          |
| Residence: City <u>Port Jefferson</u>                                                                       | State <u>NY</u>      | Country <u>US</u>                                                             | Citizenship <u>INDIA</u> |
| 5, Sea Court Lane<br>Mailing Address                                                                        |                      |                                                                               |                          |
| Mailing Address                                                                                             |                      |                                                                               |                          |
| City <u>Port Jefferson</u>                                                                                  | State <u>NY</u>      | ZIP <u>11777</u>                                                              | Country <u>US</u>        |
| Name of Additional Joint Inventor, if any:                                                                  |                      | <input type="checkbox"/> A petition has been filed for this unsigned inventor |                          |
| Given Name (first and middle [if any])                                                                      |                      | Family Name or Surname                                                        |                          |
|                                                                                                             |                      |                                                                               |                          |
| Inventor's Signature<br> | Date                 |                                                                               |                          |
| Residence: City                                                                                             | State                | Country                                                                       | Citizenship              |
| Mailing Address                                                                                             |                      |                                                                               |                          |
| Mailing Address                                                                                             |                      |                                                                               |                          |
| City                                                                                                        | State                | ZIP                                                                           | Country                  |

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**DECLARATION**
**ADDITIONAL INVENTOR(S)  
Supplemental Sheet  
Page 1 of 1**

|                                                   |  |                                                                               |  |
|---------------------------------------------------|--|-------------------------------------------------------------------------------|--|
| <b>Name of Additional Joint Inventor, if any:</b> |  | <input type="checkbox"/> A petition has been filed for this unsigned Inventor |  |
| Given Name (first and middle [if any])            |  | Family Name or Surname                                                        |  |
| H. GREG                                           |  | THOMAS                                                                        |  |
| Inventor's Signature                              |  | Date                                                                          |  |
| Residence: City VILLA RICA                        |  | State GA Country US Citizenship US                                            |  |
| 29 BROOKSIDE WAY<br>Mailing Address               |  |                                                                               |  |
| Mailing Address                                   |  |                                                                               |  |
| City VILLA RICA                                   |  | State GA ZIP 30180 Country US                                                 |  |
| <b>Name of Additional Joint Inventor, if any:</b> |  | <input type="checkbox"/> A petition has been filed for this unsigned Inventor |  |
| Given Name (first and middle [if any])            |  | Family Name or Surname                                                        |  |
| NARASIMHAN <i>[Signature]</i>                     |  | MANI                                                                          |  |
| Inventor's Signature <i>[Signature]</i>           |  | Date 08/18/2004                                                               |  |
| Residence: City Port Jefferson                    |  | State NY ZIP <i>11777</i> Country US Citizenship INDIA                        |  |
| 5, Sea Court Lane<br>Mailing Address              |  |                                                                               |  |
| Mailing Address                                   |  |                                                                               |  |
| City Port Jefferson                               |  | State NY ZIP 11777 Country US                                                 |  |
| <b>Name of Additional Joint Inventor, if any:</b> |  | <input type="checkbox"/> A petition has been filed for this unsigned Inventor |  |
| Given Name (first and middle [if any])            |  | Family Name or Surname                                                        |  |
|                                                   |  |                                                                               |  |
| Inventor's Signature                              |  | Date                                                                          |  |
| Residence: City                                   |  | State Country Citizenship                                                     |  |
| Mailing Address                                   |  |                                                                               |  |
| Mailing Address                                   |  |                                                                               |  |
| City                                              |  | State ZIP Country                                                             |  |

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